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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,596	04/13/2001	Hideji Tajima	10287.34	9347

27683 7590 05/04/2005

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EXAMINER	
CROSS, LATOYA I	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,596	TAJIMA ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 May 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 32-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 32-82 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on February 9, 2005. Claims 32-82 are pending.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 32-39, 41, 42, 45-62, 64, 65, 67-82 are rejected under 35 U.S.C. 103(a) as being obvious over US Patent 6,335,166 to Ammann et al in view of US Patent 5,047,210 to Melet.

Ammann et al disclose an automatic analyzer comprising computer controller **1000** for running high-level analyzer controlling software and a microprocessor for controlling the low-level analyzer functions (col. 9, lines 19-31). The computer controller and microprocessor are equivalent to Applicants' claimed operation/control section. The system also comprises a plurality of reaction receptacles **160,162** (vessels) and a transport mechanism **500,502** (vessel moving means) for retrieving the receptacles. Further, a shuttle assembly (conveying means) and a specimen ring **250** are provided to move the receptacles along a receptacle advancement path (col. 9, lines 41-54; col. 10, lines 5-21). With respect to Applicant's claimed separator, Ammann et al

disclose a magnetic moving structure **810** for subjecting the contents of the receptacles to a magnetic field (by magnetic structures on the sides of the receptacles as recited in claim 12), thereby causing magnetic particles in the receptacles to be drawn to the sides of the receptacles and the non-magnetic fluid to be unaffected. Thus, the magnetic moving structure is equivalent to Applicants' separator because the target analytes can be isolated. The target analytes are removed from the separated liquid by aspirator tubes **860**. See col. 41, line 24 – col. 42, line 12. Ammann et al disclose that after aspiration, wash liquid is dispensed into each vessel by way of dispenser nozzles (858) (col. 42, lines 33-39). Ammann et al disclose a mixer **400** for agitating the contents of the receptacle. At col. 26, lines 17-21, the reference teaches that the mixer may operate by rotation or other techniques such as vibration and inversion. Ammann et al disclose that the receptacles are part of a specimen ring which is rotatably driven by a motor. With respect to the pipette device, Ammann et al disclose a specimen pipette assembly or robot **450** positioned above the specimen ring **250** and pipette tip wheel, containing nozzles. The specimen pipette assembly is movable in an X,Y,Z motion to access reagent fluids and the receptacles (col. 10, line 55 – col. 11, line 23. With respect to the presence of sensors, Ammann et al teach that several sensors are mounted on the bulk fluids provided in reagent bottles. Upper sensors indicate when the bottles are full, while lower sensors indicator when the bottles are empty (col. 17, line 66- col. 18, line 4; lines

53-67). The aspirator tubes of the Ammann et al are disclosed as extending through a tube holder (main body) to which tubes are secured and extending through openings of the tube holder. The aspirator tubes have aspirator hoses which are lowered by a lift motor and drive screw (plunger) until frictionally engaged in a tiplet. See col. 39, line 61 – col. 40, line 47. The reference further discloses that several incubators **600,602,604,606** are provided and transport mechanism can insert the receptacles into the incubator or retrieve the receptacles from the incubator (col. 12, lines 47-53). With respect to the method claims, Ammann et al details the steps for carrying out an assay using the system described, wherein the computer receives instructions from an operator, the receptacles are introduced into the transport mechanism, reagents are dispensed, the mixer agitates the contents, the contents are separated using a magnetic field, the target analytes are removed and the receptacles are further moved along the processing path.

Ammann et al differ from the instantly amended claims in that there is no disclosure of an incline mechanism. Ammann et al do teach that the pipette assembly comprises a liquid drawing section and nozzles (pipette), as well as a vertical movement mechanism (robot). However, the reference fails to teach an incline mechanism.

Melet teaches a device for presenting receptacles in an automatic analyzer. The device includes a means for inclining the receptacles so that they are better suited for presentation in an analyzer, in particular so the receptacles allow better sample removal. See col. 2, lines 21-34; col. 4, lines 62-68.

It would have been obvious to one of ordinary skill in the art to incorporate an inclining means in the system of Ammann et al to allow the receptacles to tip in a manner that will allow better sample removal with the pipette assembly.

3. Claims 40, 43, 44, 63, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ammann et al and Melet as applied above and further in view of US Patent 6,017,721 to Butz.

Ammann et al and Melet fail to teach using microplates (claim 4) or centrifugation for separation (claim 7). With respect to the vessels being microplates, it would have been obvious to one of ordinary skill in the art to use microplates in Ammann et al instead of test tubes to allow for several small samples to be analyzed as one time. Such is advantageous when only a small amount of sample is available and when several assays need to be performed in a short amount of time. With respect to using a centrifuge as the separator, Butz teaches that it common to either magnetic separation (as in Ammann et al) or centrifugation to separate target analytes from

unwanted substances (col. 6, lines 51-65). It would have been obvious to one of ordinary skill in the art to incorporate a centrifuge in the system of Ammann et al to provide a means for separating the target material from the fluid suspensions.

Response to Arguments

4. Applicant's arguments filed February 9, 2005 have been fully considered but they are not persuasive. With respect to the Ammann et al reference, Applicants argue that the reference fails to teach a conveyor, dispenser, nozzle, means for moving and inclining mechanism. In response, Ammann et al do teach a conveyor, dispenser, and means for moving. As stated in the previous rejection, it would have been obvious to include an incline mechanism to the system of Ammann et al, per the teachings of Melet to better position the receptacles for analysis. Applicants argue that there is no motivation to include an incline mechanism. The Examiner disagrees. Melet teaches that it is important for the sample vessels to be positioned correctly to ensure proper removal of sample from the vessel or correct analysis of the sample inside the vessel. To fix the problem, Melet teaches using an inclining mechanism for presenting the receptacles in an automatic analyzer. In including an inclining mechanism in Ammann et al the user would be assured that the sample would be in the proper position for removal from the vessel or analysis inside the vessel.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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